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EXAMINER

YEAGER, RAYMOND P

ART UNIT

PAPER NUMBER

1619

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/593,948

Applicant(s)

MARGAM ET AL.

Examiner

RAYMOND P. YEAGER

Art Unit

1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 05 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 24 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S508)
- Paper No(s)/Mail Date 06/05/2009
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1 to 25 are pending.

Election/Restriction

Applicant's election without traverse of group II, claims 8 to 23 in the reply filed on 06/05/2009 is acknowledged.

Claims 1 to 7 and 24 to 25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on 06/05/2009. Claims 8 to 23 are examined.

Priority

Application 10/593,948 (09/22/2006) is a national stage entry of PCT/SG05/00087 per 35 USC 371 and claims foreign priority to Singapore application 200401544-2 (03/22/2004) per 35 USC 119. Receipt is acknowledged of a certified copy of the SINGAPORE 200401544-2 application which is not referred to in the oath or declaration or in an application data sheet. If this copy is being filed to obtain the benefits of the foreign filing date under 35 U.S.C. 119(a)-(d), applicant should also file a claim for such priority as required by 35 U.S.C. 119(b). If the application being examined is an original application filed under 35 U.S.C. 111(a) (other than a design application) on or after November 29, 2000, the claim for priority must be presented during the pendency of the application, and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior foreign application. See 37 CFR 1.55(a)(1)(i). If the application being examined has entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the claim for priority must be made during the pendency of the application and within the time limit set forth in the PCT and Regulations of the PCT. See 37 CFR 1.55(a)(1)(ii). Any claim for priority under 35 U.S.C. 119(a)-(d) or (f) or 365(a) or (b) not presented within the time period set forth in

37 CFR 1.55(a)(1) is considered to have been waived. If a claim for foreign priority is presented after the time period set forth in 37 CFR 1.55(a)(1), the claim may be accepted if the claim properly identifies the prior foreign application and is accompanied by a grantable petition to accept an unintentionally delayed claim for priority. See 37 CFR 1.55(c). Therefore, claims 8 to 23 are considered to have an effective filing date of 03/18/2005.

Information Disclosure Statement

The Information Disclosure Statement (1) has been reviewed. Applicants are reminded of their duty to disclose all information known to them to be material to patentability as defined in 37 CFR 1.56.

Objections – Oath

Receipt is acknowledged of papers filed under 35 U.S.C. 119 (a)-(d) based on an application filed in SINGAPORE (200401544-2) on 03/22/2004. Applicant has not complied with the requirements of 37 CFR 1.63(c), since the oath, declaration or application data sheet does not acknowledge the filing of any foreign application. A new oath, declaration or application data sheet is required in the body of which the present application should be identified by application number and filing date.

Objections – Drawings

The drawings are objected to under 37 CFR 1.83(a) because they fail to clearly show confocal images in figure 3, optical images in figure 4, and graphs of porosity profiles in figure 5 as described in the specification (page 4). Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being

amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Figure 1 recites number 2 but what the number 2 refers to is not disclosed in the instant application. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Objections – Specification

The disclosure is objected to because of the following informalities: The specification does not define or disclose the reference for number 2 on figure 1. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- Claims 8 to 11, 13, 15, 18 to 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/060508 (Publication date: 08/08/2002), Hereafter referred to as the '508 publication, in view of US patent 6,149,688 (Publication date: 11/21/2000; Filing date: 09/29/1997), hereafter referred to as the '688 patent.

Applicant claims a method of mixing two polymers (60:40 to 30:70 ratio), forming a scaffold, and leaching a polymer wherein leaching with a solvent is maximized at the surface resulting in greater porosity at the surface than the core. The polymers natural and/or synthetic are biodegradable wherein the leached polymer is more biodegradable. Polymers are blended and milled in a cryogenic mill (15-30 cycles/min, 15 impacts/sec, 20-500µm) then compressed and molded, and remove a polymer by leaching.

Determination of the scope and content of the prior art - (MPEP 2141.01)

The '508 publication teaches a method of preparing a porous scaffold for use in tissue engineering ('508 abstract) wherein at least two polymers are blended in a low temperature mill ('508, page 6, lines 24-25) to a size of 10-1000µm, the scaffold is

formed under pressure ('508, page 9, lines 3-5), and a solvent is used to dissolve the soluble particle ('508 page 16-20) (i.e. leaching) wherein the soluble particles comprise a polymer, PMMA ('508, page 14, claims 3 and 7) that will dissolve without affecting the copolymer ('508, page 9, claims 17-20) and thus at least two of the polymers have a different biodegradability (limitations in instant claims 8, 9, 11, 13, 15, 18, and 23). The '508 publication discloses a polymer ratio of 60:40 to 30:70 (limitations in instant claim 10) of aromatic polyesters and polyalkylene glycol terephthalate and polybutylene terephthalate ('508, page 4, lines 1-6; page 5, lines 13-17; and page 6, lines 1-3) (limitations in instant claims 10 and 11). As the '508 publication discloses the same particle size as the particle size in the instant application, it would be obvious to one of ordinary skill in the art to adjust the settings to optimize the particle size (limitations in instant claims 19 to 21).

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

The difference between the instant application and the '508 publication is that the '508 publication does not expressly teach a porosity gradient which increases from the core to the surface. This deficiency in the '508 publication is cured by the teachings of the '688 patent. The '688 patent teaches a porosity gradient with a dense core and a porous surface form by the removal of a binder ('688, column 4, lines 47-57) (limitations in claim 8 and 22).

Finding of prima facie obviousness - Rational and Motivation - (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide a two polymers in a copolymers form and provide sacrificial polymer to form pores from particulates by cryogenic milling, compression and molding, and leaching the sacrificial polymer as taught by the '508 publication and provide a porosity gradient as taught in the '688 patent.

One of ordinary skill in the art would have been motivated to do this because the '688 patent provides an implant with a porosity which allows bone tissue ingrowth for repair ('688, column 2, lines 44-48 and column 4, lines 57-58).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

- Claims 8, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/060508 (Publication date: 08/08/2002), Hereafter referred to as the '508 publication, in view of US patent 6,149,688 (Publication date: 11/21/2000; Filing date: 09/29/1997), the '688 patent as in claims 8-11, 13, 15, 18 to 23 are above and further in view of US Patent 6,063,894 (Publication date: 05/16/2000; Filing date: 10/09/1998), hereafter referred to as the '894 patent.

Applicant claims a method of mixing two natural and/or synthetic polymers by forming a scaffold, and leaching a polymer wherein leaching with a solvent is maximized at the surface resulting in greater porosity at the surface than the core. Polymers are blended and milled in a cryogenic mill then compression molded, and leached in an ultrasonic bath (1-40 KHz, 5-120 min, and 25-50°C).

Determination of the scope and content of the prior art - (MPEP 2141.01)

The combination of the '508 publication and the '688 patent teaches as set forth *supra*, a method of preparing a porous scaffold for use in tissue engineering wherein at least two polymers are blended in a cryogenic mill, the scaffold is formed under pressure, and a solvent is used to dissolve the soluble polymer such that a porosity gradient forms with greatest porosity at the surface.

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

The difference between the instant application and the '508 publication in view of the '688 patent is that the combination of the '508 publication and the '688 patent does not

expressly teach the use an ultrasonic bath. This deficiency in the combination of the '508 publication and the '688 patent is cured by the teachings of the '894 patent. The '894 patent teaches the extraction of a soluble compound ('894, column 4, lines 19-27) at 15-100 KHz ('894, column 6, lines 34-37) and a temperature of 35 -180°C ('894, column 18, claim 19). These ranges overlap and make obvious the instantly claimed ranges (instant claims 16 and 17). Further, the '894 patent provides a working example wherein the ultrasound was performed for 60 minutes ('894, column 16, example 11).

Finding of prima facie obviousness - Rational and Motivation - (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to cryogenically mill, compress, and leach a sacrificial polymer from a composition with at least two polymers as taught by the combination of the '508 publication and the '688 patent and leach the sacrificial polymer in an ultrasonic bath as taught in the '894 patent.

One of ordinary skill in the art would have been motivated to do this because the '894 patent teaches the enhancement of mechanical properties of the polymer by leaching compounds in an ultrasonic bath ('894, column 4, lines 19-27).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

- Claims 8, 13, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/060508 (Publication date: 08/08/2002), Hereafter referred to as the '508 publication, in view of US patent 6,149,688 (Publication date: 11/21/2000; Filing date: 09/29/1997), the '688 patent as in claims 8-11, 13, 15, 18 to 23 are above and further in

view of US patent application publication 2004/0258732 (Publication date: 12/23/2004; Filing date: 11/20/2002), hereafter referred to as the '732 publication.

Applicant claims a method of mixing two natural and/or synthetic polymers by forming a scaffold, and leaching a polymer wherein leaching with a solvent is maximized at the surface resulting in greater porosity at the surface than the core. Polymers are blended and milled in a cryogenic mill then compression molded (0-20 MPa and 25-80°C), and a polymer is removed by dissolution.

Determination of the scope and content of the prior art - (MPEP 2141.01)

The combination of the '508 publication and the '688 patent teaches a method of preparing a porous scaffold for use in tissue engineering wherein at least two polymers are blended in a cryogenic mill, the scaffold is formed under pressure, and a solvent is used to dissolve the soluble polymer such that a porosity gradient forms with greatest porosity at the surface. Further, the '688 patent teaches a pressure of 6.9 to 14.8 MPa is used to consolidate powder to make a bone implant ('688, column 4, lines 28-31).

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

The difference between the instant application and the combination of the '508 publication and the '688 patent is that the combination of the '508 publication and the '688 patent does not expressly provide an embodiment comprising all the limitations of the compression molding. This deficiency in the combination of the '508 publication and the '688 patent is cured by the teachings of the '732 publication. The '732 publication teaches a porous, copolymeric implant material comprising a porous block copolymer ('732, page 4, paragraph 22) formed by compression molding at about 70°C ('732, page 5, paragraph 50) and a compression strength of approximately 1MPa to 5 MPa ('732, page 6, paragraph 58).

Finding of prima facie obviousness - Rational and Motivation - (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to cryogenically mill, compress, and leach a sacrificial polymer from a composition with at least two polymers as taught by the combination of

the '508 publication and the '688 patent and to compression mold with the parameters as taught in the '732 patent.

One of ordinary skill in the art would have been motivated to do this because the '732 patent discloses a porous polymeric material used for bone tissue regeneration or artificial cartilage and various other clinical applications ('732, page 4, paragraphs 22, 23, and 30) and also discloses compression molding can be used to control the pore size in a structure ('732, page 7, paragraph 61). Thus one of ordinary skill in the art would understand that compression molding is well-known in the art and has been used to control the porosity of moldable structures. In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

- Claims 8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 02/060508 (Publication date: 08/08/2002), Hereafter referred to as the '508 publication, in view of US patent 6,149,688 (Publication date: 11/21/2000; Filing date: 09/29/1997), the '688 patent as in claims 8-11, 13, 15, 18 to 23 are above and further in view of US Patent 6,712,845 (Publication date: 03/30/2004; Filing date: 04/24/2001), hereafter referred to as the '845 publication.

Applicant claims a method of mixing two natural and/or synthetic polymers by forming a scaffold, and leaching a polymer wherein leaching with a solvent is maximized at the surface resulting in greater porosity at the surface than the core. Polymers are blended and milled in a cryogenic mill then compression molded, and leached in an ultrasonic bath (1-40 KHz, 5-120 min, and 25-50°C).

Determination of the scope and content of the prior art - (MPEP 2141.01)

The combination of the '508 publication and the '688 patent teaches a method of preparing a porous scaffold for use in tissue engineering wherein at least two polymers are blended in a cryogenic mill, the scaffold is formed under pressure, and a solvent is used to dissolve the soluble polymer such that a porosity gradient forms with greatest porosity at the surface.

**Ascertainment of the difference between the prior art and the claims
(MPEP 2141.02)**

The difference between the instant application and the combination of the '508 publication and the '688 patent is that the combination of the '508 publication and the '688 patent does not expressly teach the specific solvents used to leach the sacrificial polymer. This deficiency in the combination of the '508 publication and the '688 patent is cured by the teachings of the '845 patent. The '845 patent teaches the removal of one polymer from a coating comprising at least two polymers and provides an embodiment where the process may be repeated ('845, column 8, line 49 to column 9, line 40) using solvents such as acetone, chloroform, and other ('845, column 3, lines 44-55) (limitation in claim 12).

Finding of prima facie obviousness - Rational and Motivation - (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to cryogenically mill, compress, and leach a sacrificial polymer from a composition with at least two polymers as taught by the combination of the '508 publication and the '688 patent and leach the sacrificial polymer with the solvents taught in the '845 patent.

One of ordinary skill in the art would have been motivated to do the '845 patent provides a method of using solvents to remove a polymer from a copolymeric surface ('894, column 2, lines 8-14 and column 5, lines 17-22) and thus providing that the method of using a solvent to leach a polymer from a copolymer would be known to one of ordinary skill in the art.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RAYMOND P. YEAGER whose telephone number is (571) 270-7681. The examiner can normally be reached on Mon - Thurs 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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